To assess the action of *Cephalandra indica*, a homoeopathic mother tincture on hba1c in type 2 diabetes mellitus in age group 30-75 years as add on medicine along with conventional antidiabetics

Evaluar la acción de *Cephalandra indica*, una tintura madre homeopática sobre la hba1c en diabetes mellitus tipo 2 en el grupo de edad de 30 a 75 años como añadido a medicamentos junto con antidiabéticos convencionales

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ABSTRACT

The worldwide prevalence of DM has risen dramatically over the past two decades, from an estimated 30 million cases in 1985 to 177 million in 2000. DM is a sedentary life-style disorder where 79.4 Million individuals in India may have affect of Diabetes Mellitus by 2030.Homoeopathy plays an important role by giving medicine by organ specific medicines given in mother tinctures..Methods: This is a clinical study on Diabetes Mellitus Type 2 individuals of age group 30-75 years. Total 32 patients of Pre- diagnosed and newly diagnosed DM are enrolled of which 30 patients (Male & female) are present till the end of the study where as 2 individuals dropped out from study. The study is done by assessing the Fasting, Post prandial blood sugar level and HbA1c levels. Result:Of 30 patients who completed the study, 30 are the experimental and were given medication there was marked improvement in 23 of the cases and there was no improvement in 7 cases. The medicine prescribed was *Cephalandra indica* in tincture considering its antidiabetic properties.

Keywords: Diabetes mellitus type 2, HbA1C, Homoeopathy, *Cephalandra indica.*

RESUMEN

La prevalencia mundial de DM ha aumentado dramáticamente en las últimas dos décadas, de aproximadamente 30 millones de casos en 1985 a 177 millones en 2000. La DM es un trastorno del estilo de vida

sedentario en el que 79,4 millones de personas en la India podrían tener diabetes mellitus para 2030. La homeopatía juega un papel importante al administrar medicamentos mediante medicamentos específicos de órganos administrados en tinturas madre. Métodos: Este es un estudio clínico en personas con diabetes mellitus tipo 2 del grupo de edad de 30 a 75 años. Se inscribieron un total de 32 pacientes con DM prediagnosticada y recién diagnosticada, de los cuales 30 pacientes (hombres y mujeres) están presentes hasta el final del estudio, mientras que 2 personas abandonaron el estudio. El estudio se realiza evaluando el nivel de azúcar en sangre en ayunas, posprandial y los niveles de HbA1c. Resultado: De 30 pacientes que completaron el estudio, 30 son experimentales y recibieron medicación, hubo una mejora marcada en 23 de los casos y no hubo mejora en 7 casos. El medicamento recetado fue Cephalandra indica en tintura considerando sus propiedades antidiabéticas.

Palabras clave: Diabetes mellitus tipo 2, HbA1C, Homeopatía, Cephalandra indica.

INTRODUCTION

Way of life advance wellbeing through sufficient nutritious food, legitimate rest and effective climate. Because of quick monetary turn of events, urbanization, globalization, expanding westernization of way of life there is predominance of way of life sicknesses has disturbing extents among Indians lately. The disease is maintained due to some cause which tend to obstruct the path of cure in Chronic diseases. Universally, Of all deaths,70% are because of non- communicable sicknesses, India represents about the second biggest nation in cases of diabetes, as per WHO each twelfth Indian is a diabetic.1.4 million deaths because of diabetes which is considered as "*Worldwide Burden of Diseases* " Universally, Diabetes mellitus a rising medical condition, putting impractical expectations on people and in the general public. Notwithstanding the morbidity and mortality related with retinopathy, neuropathy, nephropathy, cardiovascular infection stays as the main source of death. Lifestyle disorders are ice-berg diseases, which increases both in rate and prevalence around the world. When considered as the sickness of middleaged and older, yet these days it is the disturbing infection of more youthful age as well. The illness which disintegrates the general advancement of the country which itself influences the efficient time of life.

DIABETES MELLITUS

Diabetes mellitus is a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbance of carbohydrates, fat and protein metabolism resulting fromdefects in insulin secretion, action or both.[2]

CLASSIFICATION

Diabetes is classified on basis of pathogenic process that leads to hyperglycemia. Two broadcategories of

DM are designated as TYPE 1 DM and TYPE 2 DM.[1]

Type 1 is termed as Insulin dependent Diabetes Mellitus

- Type I diabetes mellitus is due to deficiency of insulin because of destruction of β-cells inislets of Langerhans.

- This type of diabetes mellitus may occur at any age of life.

- But, it usually occurs before 40 years of age and persons affected by thisrequire insulin injection.

  Type 2 is termed as Noninsulin dependent Diabetes Mellitus.

- Type II diabetes mellitus is due to insulin resistance (failure of insulin receptors to giveresponse to insulin).

- So, the body is unable to use insulin.

- About 90% of diabetic patients have type II diabetes mellitus.

  It usually occurs after 40 years. Only some forms of Type II diabetes require insulinOther types include Gestational Diabetes.

  TYPE 2 DIABETES: Type 2 DM present with the characteristic symptoms of polyuria, polydipsia and polyphagia with weakness and weight loss, many type 2 diabetics are asymptomatic and remain silent for many years and at diagnosis may have features of long termcomplications like neuropathy (tingling, numbness, paraesthesia of lower limbs), retinopathy oreven nephropathy.[1]

COMPLICATIONS

Acute: 1. Diabetic Ketoacidosis.

2.Hyperglycemic hyperosmolar state

Chronic: MICROVASCULAR

1.Retinopathy
2.Macular edema
3.Nephropathy

MACROVASCULAR

1.Coronaryartery disease

2.peripheral arterial disease

3.cerebrovascular disease

Treatment: Diabetes mellitus type 2 can be treated by homoeopathic medicines.Many cases of diabetes mellitus have been treated with homoeopathic mother tinctures with antidiabetic properties ,such as Cephalandra Indica.

Cephalandra indica

Cephalandra indica exhibit various Phytochemical like saponins, glavonoids, sterols and alkaloids. These Phytochemicals are responsible for numerous pharmacological activities. Phyto is the Greek word for plant. There are many families of Phytochemical and they help the human body in a variety of ways. This may protect from a host of disease. Cephalandra indica roots contain flavonoid glycoside ombuin 3 arabinofuranoside, Triterpenoid, saponin coccinioside – k, stigmast – 7 –en 3-one, Lupeol, Beta amyrin and beta sitosterol and whole plant is contain aspartic acid, glutamic acid, asparagines, tyrosine, Histidine, phenylalanine and threonine valine arginine. This plant fruits contain taraxerone, taraxerol and ethylcholest-5-en-3beta glucoside, carotene lycopene cryptoxanthin and apo 6 lycopenal, beta sitosterol and taraxero. Steam and leaves contain beta sitosterol,cephalandrol, cephaladnrine A&B, Heptacosane, this aerial part contain heptacosane, cephalandrol, beta sitosterol alkaloids cephalandrine A and cephalandrine B. Pharmacological studies: Antidiabetic activity: Ghose in 1952 introduced this medicine in Homoeopathy through proving and gave few case reportsabout its usefulness in the treatment of diabetes mellitus in mother tincture. The study concluded that continuous administration of C. indica reduces increased level of serum lipidssecondary to the diabetic state.

MATERIAL AND METHODS

Study design: A experimental clinical study was carried out in Bharati Vidyapeeth medical foundation Homoeopathic Hospital ,Pune.

Study duration: The was conducted approximately for 18 months.

Statistical method: Paired t-test and Descriptive statistics of the Fasting- Blood Glucose level mg/dl ,Post prandial blood sugar level mg/dl,HbA1cbefore and after the intervention. P Value <0.001, Considered to be statistically highly significant.

Paired t-test and Descriptive statistics of the Fasting- BloodGlucose level mg/dl ,Post prandial blood sugar level mg/dl,HbA1cbefore and after the intervention. P Value <0.001, Considered to be statistically highly significant.

Hence there is a significant difference in the HbA1c,fasting blood sugar levels ,post prandial blood sugar level before and after the intervention.A test used: Paired t-test.

Outcome measures: The outcome measures are calculated by comparing the previous and after values of HbA1c,fasting blood sugar levels and post prandial blood sugar levels. Paired t-test and Descriptive statistics of the Fasting- Blood Glucose level mg/dl ,Post prandial blood sugar level mg/dl,HbA1cbefore and after the intervention.These tests help to establish whether the changes observed before and after treatment were significant or not.

Sampling procedure: Sample size will be minimum 30 cases with 5 follow up. Cases were selected from OPD ,IPD of Bharati Vidyapeeth medical foundation Homoepathic Hospital, peripheral OPD and various rural and urban camp series.

Selection of remedy: After careful and detail case study *Cephalandra indica*. The remedy was administered in mother tincture.

Drug dispensing: Will be dispensed in mother tincture 10 drops thrice in 30 ml of water.

RESULTS

Of 30 patients who completed the study, 30 are the experimental and were given medication there was marked improvement in 23 of the cases and there was no improvement in 7 cases.

Before treatment, HbA1c was *7.62$\pm$ 0.52* (mean$\pm$ SD) which reduces to *7.53 $\pm$ 0.54*after treatment.

Before treatment, Fasting- Blood glucose level mg/dl was *144.3$\pm$ 23.08* (mean$\pm$ SD) which reduces to *135.5$\pm$ 19.15* after treatment.

Before treatment, Pp- Blood glucose level mg/dl was *202.2 $\pm$ 43.61* (mean$\pm$ SD) which reduces to *190.3$\pm$ 36.34* after treatment.

DISCUSSION

Diabetes mellitus type 2 is a metabolic disorder characterized by Hyperglycemia with clinical features Polydipsia, Polyuria, Polyphagia. DM is a sedentary life-style disorder where 79.4 Million individuals in India may have affect of Diabetes Mellitus by 2030.

The DM is due to impaired insulin secretion and abnormal fat metabolism in obese person with BMI > 25Kg/m^2. Also the risk of DM is increased in individuals with familial tendency of DM, in persons whose physical activity is decreased.

There are factors which also interfere with the recovery like stress,over alcohol consumption, smoking, improper nutrition etc; which are elicited by a detailed case taking and the cause which obstruct the prognosis is noted and the Homeopathic Remedy is prescribed.

This study is done on Pre-diagnosed and newly diagnosed diabetes mellitus, 30 individuals of age group 30-75 years (Male & Female) from outpatient department of Bharati Vidyapeeth Deemed University Homoeopathic College & Research Centre, Katraj, and Pune.out of which 30 patient have completed the study and were give homoeopathic mother tincture Cephalandra Indica.Out of 30 cases results show 23 marked improvement and 7 cases which HbA1c was not improved >0.5.This shows there is a specific significance when the medicine selected has antidiabetic properties which reduces the blood sugar level.

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Before treatment, HbA1c was $7.62\underline{+}$ 0.52 (mean$\underline{+}$ SD) which reduces to $7.53 \underline{+}$ 0.54after treatment.

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Before treatment, Pp- Blood glucose level mg/dl was 202.2 $\underline{+}$ 43.61 (mean$\underline{+}$ SD) which reduces to 190.3$\underline{+}$ 36.34 after treatment.

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Table1: Distribution of patients according to age

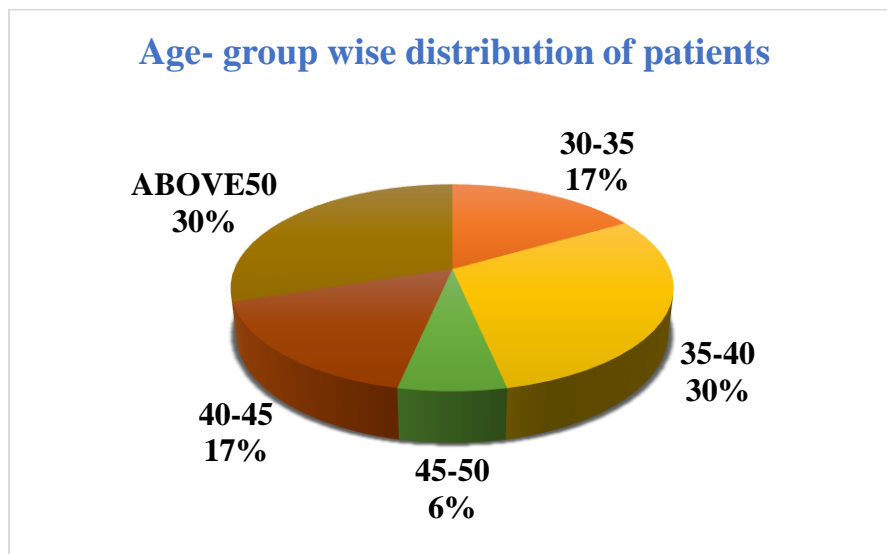| Age Group	No of patients	Percentage
30-35	5	16.67%
35-40	9	30.00%
45-50	2	6.67%
40-45	5	16.67%
ABOVE50	9	30.00%

Figure 1: Pie diagram representing Age-wise distribution of patients

Above table1 and diagram(figure1) show that 30% of the patients had an age above 50 years, 6% had an age between 45-50 years , 17% had an age between 40-45 years, 30% of the patients had an age between 35-40 years, 17% of patients had age between 30-35 years in the study.

Table2: Distribution of Patients according to Gender

Gender	Number of patients	Percentage
FEMALE	13	43.33%
MALE	17	56.67%
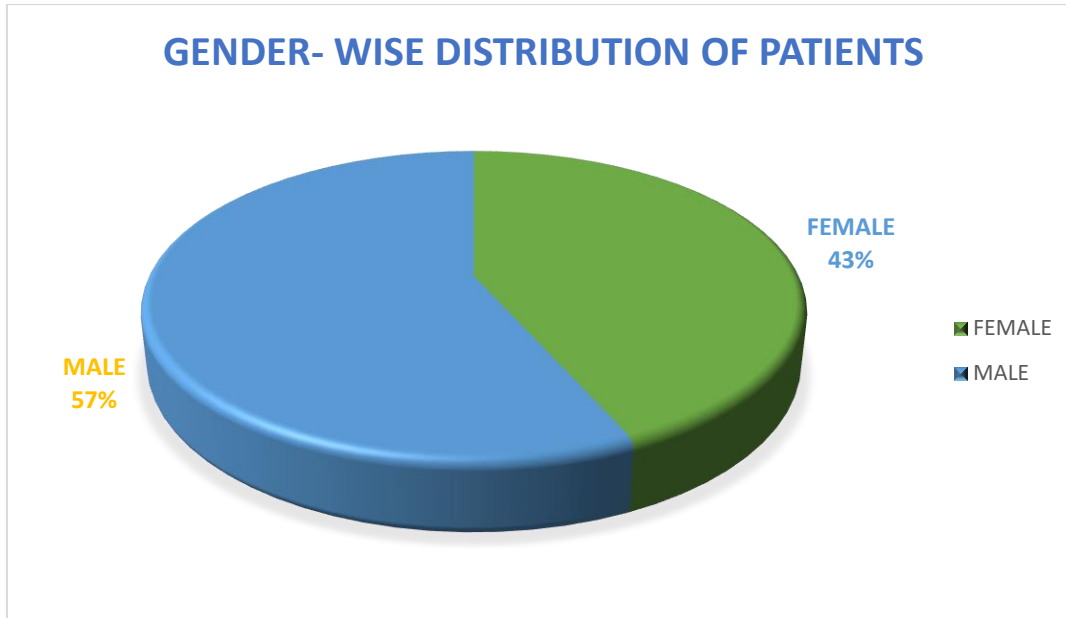
HYPOTHESIS TESTED:

H_0: Cephalandra indica Q is not effective in the management of type 2 diabetes mellitus in the age group of 30-75 years.

Vs

H_1: Cephalandra indica Q is effective in the management of type 2 diabetes mellitus in the age group of 30-75 years.

Table 3: Paired t-test and Descriptive statistics of the HbA1c before and after the intervention.

HbA1c	N	Mean$\pm$ SD	T Statistic Value	P-Value
before intervention	30	7.62$\pm$ 0.52	4.65	0.000**
after intervention	30	7.53 $\pm$ 0.54		
Mean difference		0.087 $\pm$ 0.10	95% CI for Mean difference	(0.049, 0.126)

P Value <0.001, Considered to be statistically highly significant.

Hence there is a significant difference in the HbA1c before and after the intervention.

A test used: Paired t-test, **: Highly Significant Difference, T Statistic-value: Test Statistic value.
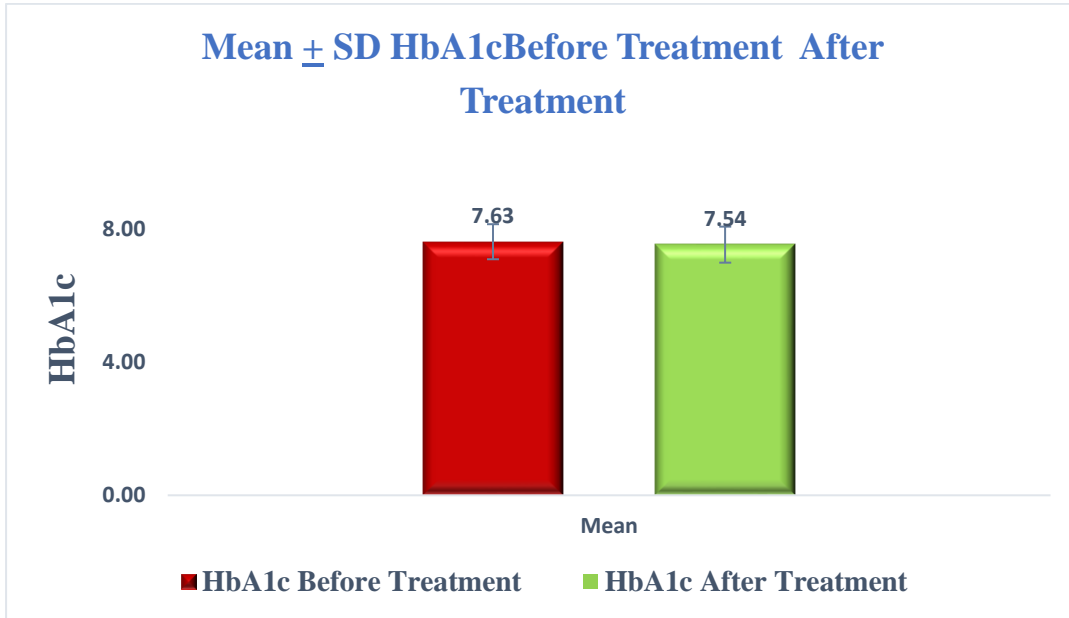

Figure 3: Bar diagram representing the Average + SD of HbA1c before and after the intervention.

Table 3 and Fig 3 show descriptive Statistics and paired t-test results of the HbA1c before and after the intervention in the management of Diabetes Mellitus Type *2*.

Before treatment, HbA1c was *7.62+ 0.52* (mean+ SD) which reduces to *7.53 + 0.54*after treatment.

To test the hypothesis of whether the average HbA1c in patients, before and after the intervention of Homoeopathic medicine remains the same or not, the Paired t-test is used.
T-statistic value is 4.65 with a p-value of 0.000 ** highly significant.

We reject Ho and conclude that there is a significant difference in average HbA1c before and after the intervention of Homoeopathic medicine.

Table 4: Paired t-test and Descriptive statistics of the Fasting- Blood Glucose level mg/dl before and after the intervention.

Fasting- Blood glucose level mg/dl	N	Mean$\pm$ SD mg/dl	T Statistic Value	P-Value
before intervention	31	144.3$\pm$ 23.08	4.54	0.000**
after intervention	31	135.5$\pm$ 19.15		
Mean difference		8.8$\pm$ 10.61	95% CI for mean difference: ((4.83, 12.76)	

P Value <0.001, Considered to be statistically highly significant.

Hence there is a significant difference in the Fasting- Blood glucose level mg/dl before and after the intervention.

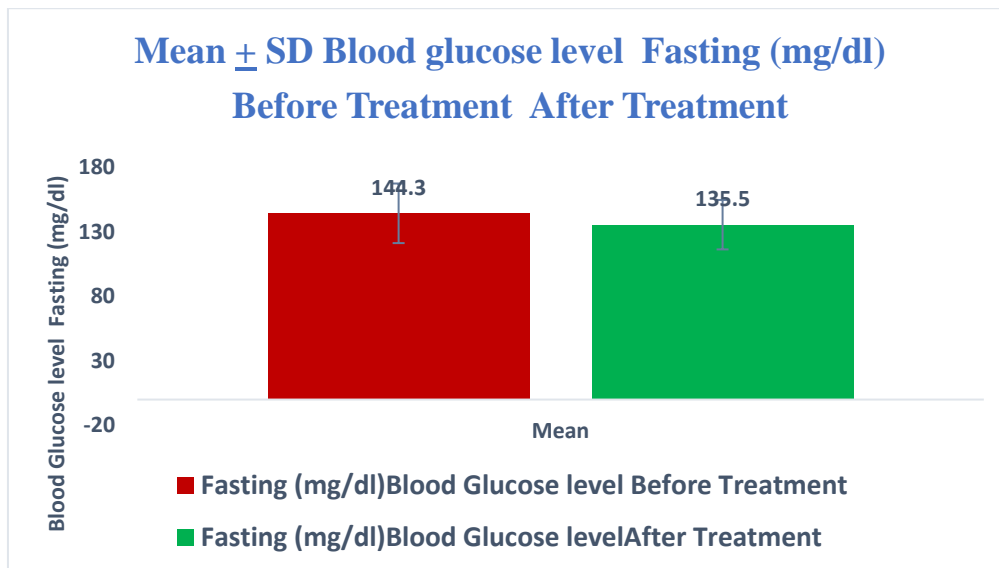 A test used: Paired t-test, **: Highly Significant Difference, T Statistic-value: Test Statistic value.

Figure 4: Bar diagram representing the Average $\pm$ SD of Fasting- Blood glucose level mg/dl before and after the intervention.

Table 4 and Fig 4 show descriptive Statistics and paired t-test results of the Fasting- Blood glucose level mg/dl before and after the intervention of Cephalandra indica Q in Diabetes Mellitus Type 2.

Before treatment, Fasting- Blood glucose level mg/dl was *144.3$\pm$ 23.08* (mean$\pm$ SD) which reduces to *135.5$\pm$ 19.15* after treatment.

To test the hypothesis of whether the average Fasting- Blood glucose level (mg/dl) in patients, before and after the intervention of Homoeopathic medicine remains the same or not, the Paired t-test is used.

The T-statistic value is 4.54 with a p-value of 0.000 ** highly significant.

We reject Ho and conclude that there is a significant difference in average Fasting- Blood glucose level (mg/dl) before and after the intervention in Homoeopathic medicine.

Table 5: Paired t-test and Descriptive statistics of the Pp- Blood glucose level mg/dl before and after the intervention.

Pp- Blood glucose level mg/dl	N	Mean$\pm$ SD	T Statistic Value	P-Value
before intervention	30	202.2 $\pm$ 43.61	4.26	0.000**
after intervention	30	190.3$\pm$ 36.34		
Mean difference		11.93 $\pm$ 15.33	95% CI for mean difference: (6.20, 17.66)	

P Value <0.001, Considered to be statistically highly significant.

Hence there is a significant difference in the Pp- Blood Glucose level mg/dl before and after the intervention.

A test used: Paired t-test, **: Highly Significant Difference, T Statistic-value: Test Statistic value.
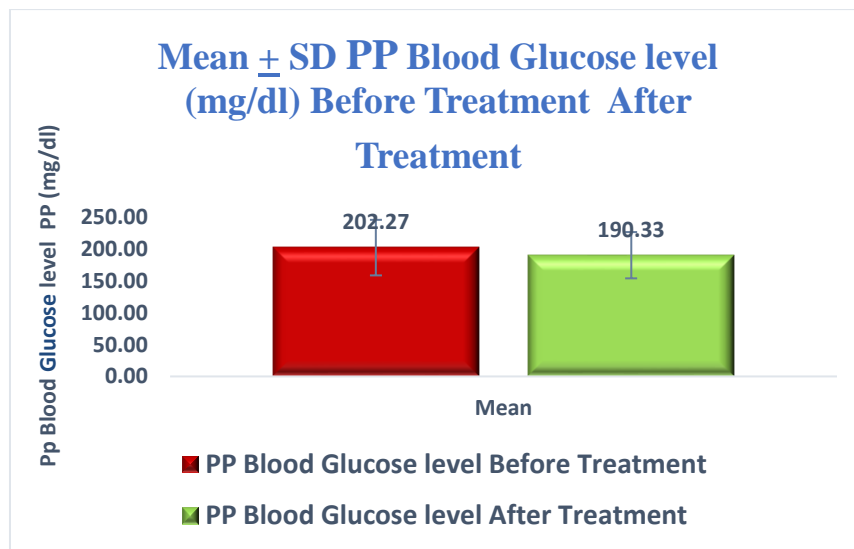

Figure 5: Bar diagram representing the Average $\pm$ SD of Pp- Blood glucose level mg/dl before and after the intervention.

Table 5 and Fig 5 show descriptive Statistics and paired t-test results of the Pp- Blood glucose level mg/dl before and after the intervention of Cephalandra indica Q in Diabetes Mellitus Type 2.

Before treatment, Pp- Blood glucose level mg/dl was *202.2 ± 43.61* (mean± SD) which reduces to *190.3± 36.34* after treatment.

To test the hypothesis of whether the average Pp- Blood glucose level (mg/dl) in patients, before and after the intervention of Homoeopathic medicine remains the same or not, the Paired t-test is used.
T-statistic value is 4.26 with a p-value of 0.000 ** highly significant.

We reject Ho and conclude that there is a significant difference in average Pp- Blood glucose level (mg/dl) before and after the intervention in Homoeopathic medicine.

From Table 3,4 5 we can conclude that Cephalandra indica Q is effective in the management of type 2 diabetes mellitus in the age group of 30-75 years.

Table 6: Descriptive statistics of the HbA1c ,Fasting- Blood glucose level mg/dl, Pp- Blood glucose level mg/dl before and after the intervention.

| Variable under study	N	Mean ±SD	Minimum	Maximum
HbA1c Before Treatment	30	7.62± 0.52	6.7	8.5
HbA1c After Treatment	30	7.53 ± 0.54	6.28	8.4
Fasting Blood glucose level mg/dl Before Treatment	30	144.3± 23.08	100	189
Fasting Blood glucose level mg/dl After Treatment Fasting	30	135.5± 19.15	100	179
Pp Blood glucose level mg/dl Before Treatment PP mg/d	30	202.2 ± 43.61	140	267
Pp Blood glucose level mg/dl After Treatment PP	30	190.3± 36.34	140	260
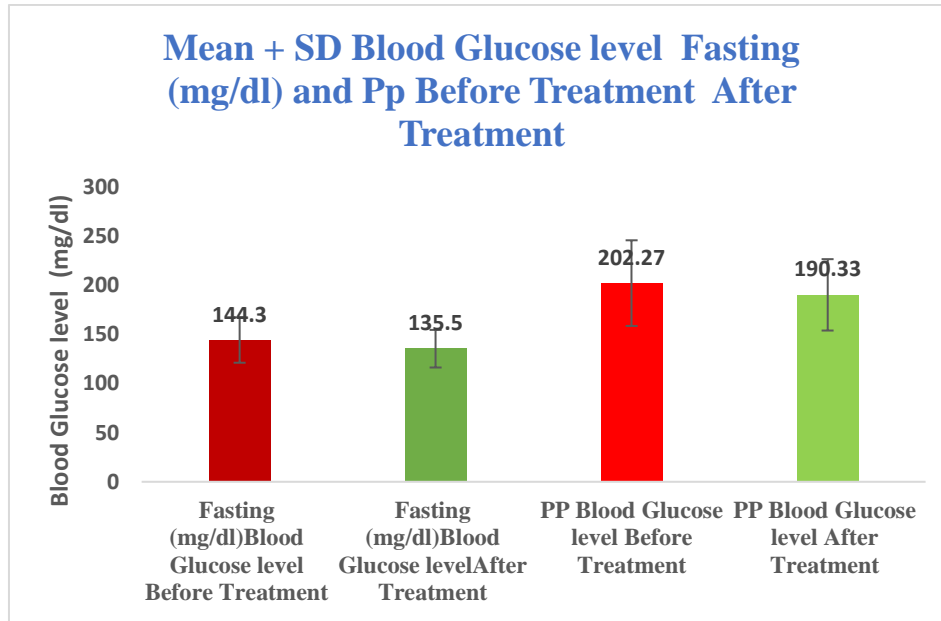
Figure 6a: Bar diagram representing the Average ± SD of fasting and Pp- Blood glucose level mg/dl before and after the intervention.

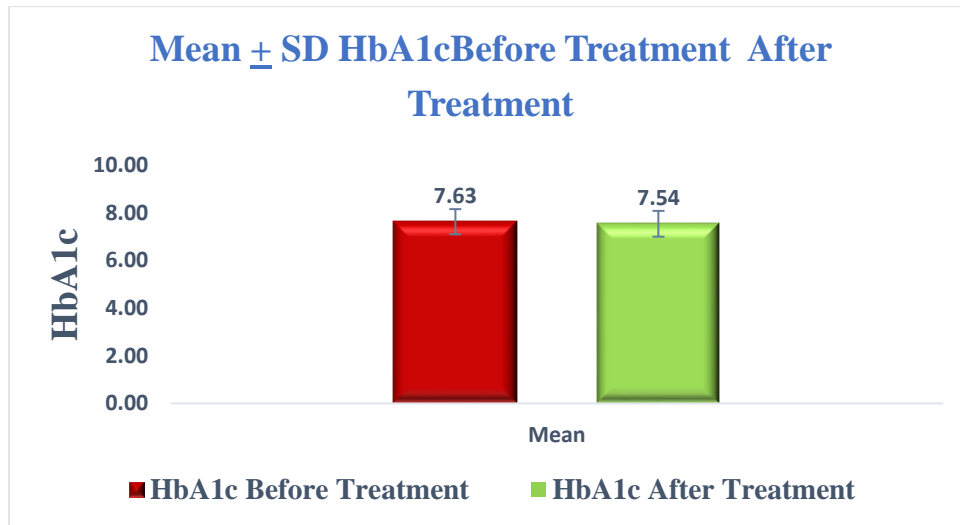

Figure 6b: Bar diagram representing the Average ± SD of HbA1c before and after the intervention.

Table 6 and Figure 6a and 6b show the descriptive statistics of the HbA1c, Fasting- Blood glucose level mg/dl, Pp-Blood glucose level mg/dl before and after the intervention.